VASCULAR DEVICE FOR VALVE LEAFLET APPOSITION

This application claims priority from U.S. Provisional patent application no. 60/214,120, filed June 26, 2000, the entire contents of which is incorporated herein by reference.

BACKGROUND

Technical Field

This application relates to a vascular device and more particularly to a vascular device for approximating vein valve leaflets for treating venous valve insufficiency.

Background of Related Art

Veins in the body transport blood to the heart and arteries carry blood away from the heart. The veins have one-way valve structures in the form of leaflets disposed annularly along the inside wall of the vein which open to permit blood flow toward the heart and close to prevent back flow. That is, when blood flows through the vein, the pressure forces the valve leaflets apart as they flex in the direction of blood flow and move towards the inside wall of the vessel, creating an opening therebetween for blood flow. The leaflets, however, do not normally bend in the opposite direction and therefore return to a closed position to prevent blood flow in the opposite, i.e. retrograde, direction after the pressure is relieved. The leaflet structures, when functioning properly, extend radially inwardly toward one another such that the tips contact each other to block backflow of blood.

In the condition of venous valve insufficiency, the valve leaflets do not function properly as they thicken and lose flexibility, resulting in their inability to extend sufficiently radially inwardly to enable their tips to come into sufficient contact with each other to prevent retrograde blood flow. The retrograde blood flow causes the buildup of hydrostatic pressure on the residual valves and the weight of the blood dilates the wall of the vessel. Such retrograde blood flow, commonly referred to as reflux, leads to swelling and varicose veins, causing great discomfort and pain to the patient. Such retrograde blood flow, if left untreated can also cause venous stasis ulcers of the skin and

subcutaneous tissue. There are generally two types of venous valve insufficiency: primary and secondary. Primary venous valve insufficiency is typically a condition from birth, where the vein is simply too large in relation to the leaflets so that the leaflets cannot come into adequate contact to prevent backflow. More common is secondary venous valve insufficiency which is caused by clots which gel and scar, thereby changing the configuration of the leaflets, i.e. thickening the leaflets creating a "stub-like" configuration. Venous valve insufficiency can occur in the superficial venous system, such as the saphenous veins in the leg, or in the deep venous system, such as the femoral and popliteal veins extending along the back of the knee to the groin.

A common method of treatment of venous valve insufficiency is placement of an elastic stocking around the patient's leg to apply external pressure to the vein, forcing the walls radially inwardly to force the leaflets into apposition. Although sometimes successful, the tight stocking is quite uncomfortable, especially in warm weather, as the stocking must be constantly worn to keep the leaflets in apposition. The elastic stocking also affects the patient's physical appearance, thereby potentially having an adverse psychological affect. This physical and/or psychological discomfort sometimes results in the patient remove the stocking, thereby preventing adequate treatment.

Another method of treatment has been developed to avoid the discomfort of the stocking. This method involves major surgery requiring the implantation of a cuff internally of the body, directly around the vein. This surgery requires a large incision, resulting in a long patient recovery time, scarring and carries the risks, e.g. anesthesia, inherent with surgery.

Another invasive method of surgery involves selective repairing of the valve leaflets, referred to as valvuloplasty. In one method, sutures are utilized to bring the free edges of the valve cusp into contact. This procedure is complicated and has the same disadvantages of the major surgery described above.

It would therefore be advantageous to provide a method and device to minimally invasively treat venous valve insufficiency without requiring an outer stocking or internal cuff. Such device would thereby avoid the physical and psychological discomfort of an external stocking as well as avoid the risk, complexity and expense of surgically

implanted cuffs. Such device would advantageously be inserted minimally invasively, i.e. intravascularly, and function to effectively bring the valve leaflets into apposition.

SUMMARY

The present invention overcomes the problems and deficiencies of the prior art by providing an intravascular device which brings the vessel wall adjacent the vein valve radially inwardly to bring valve leaflets into apposition. The present invention, in one aspect, provides a vascular device movable from a collapsed insertion position having a first diameter to an expanded position having a second larger diameter. A plurality of vessel engaging members extend outwardly from the device for securely engaging the internal wall of a vessel upon expansion of the device to the second expanded position. The vessel engaging members pull the internal wall of the vessel radially inwardly upon movement of the device from the second expanded position toward a first expanded position having a third diameter greater than the first diameter and smaller than the second diameter.

The device is preferably composed of shape memory material and the first expanded position preferably substantially corresponds to the memorized position of the device. In one embodiment, the device is initially movable from the collapsed position to the first expanded position in response to exposure to body temperature and is subsequently movable to the second expanded position by mechanical means or an inflatable balloon positioned within the device. In another embodiment, the device is movable from the collapsed position to the second expanded position by substantial simultaneous exposure to body temperature and expansion by an expandable member.

The vessel engaging members preferably extend from the distal and proximal portions of the device and have sharp ends to limit axial movement of the vessel wall and barbs to limit radial movement of the vessel wall to enhance retention (securement) of the vessel. The vessel engaging members preferably extend substantially parallel to a longitudinal axis of the device in the collapsed position and substantially perpendicular to the longitudinal axis in the extended position.

In one embodiment, in the collapsed position the middle portion of the device includes a plurality of longitudinal strips with a gap between adjacent strips. In this embodiment, the vessel engaging member is formed by a cut in the respective

longitudinal strip and the longitudinal strips buckle radially outwardly upon movement of the device to the first expanded position.

In another embodiment of the present invention, the device includes a plurality of longitudinal strips, each terminating at opposing ends in one of the vessel engaging members. A substantially straight slot can be formed in each of the longitudinal strips in the collapsed position of the device, each slot preferably transforming to a substantially diamond shape when the device is moved to the first expanded position.

In another aspect of the present invention, a vascular device is provided comprising a tubular–like member expandable from a collapsed configuration to an expanded configuration and having a plurality of hooks extending from the tubular member at the proximal end and the distal end. The hooks extend substantially parallel to the longitudinal axis in the collapsed position and substantially perpendicular to the longitudinal axis in the extended position. Barbs may be provided adjacent the hooks for limiting radial movement of a vessel wall engaged by the barbs.

In another aspect of the present invention, a vascular device is provided comprising a tubular-like member expandable from a collapsed configuration to an expanded configuration. A plurality of vessel engaging members with penetrating tips extend from the proximal, distal and intermediate portions. Expansion of the member to the expanded configuration causes the distal and proximal portions to move axially inwardly and the intermediate portion to buckle radially outwardly to enable the vessel engaging members to securely engage the vessel wall.

In another aspect of the present invention, an expandable vascular device is provided comprising a framework movable from a collapsed configuration for delivery to a target vessel to an expanded configuration for retaining the vessel. The framework is formed by a plurality of longitudinal strips with adjacent longitudinal strips formed by connecting ribs, and each of the longitudinal strips terminating at opposing ends in a vessel wall penetrating member to engage the vessel wall. In this embodiment, a longitudinal slot is preferably formed in each of the longitudinal strips such that the longitudinal slot forms a substantially diamond shaped slot in the expanded configuration of the device. The longitudinal slots are preferably in substantial axial alignment. The connecting ribs can also be in substantial axial alignment.

The present invention also provides a vascular system comprising a balloon catheter having an elongated shaft and an expandable balloon and a vascular device mounted over the expandable balloon and composed of shape memory material and having a collapsed position and a memorized position. The vascular device is expandable to an expanded position to engage the vessel walls and returnable substantially to the memorized position to bring the walls radially inwardly.

In one embodiment the vascular device is expandable first to the memorized condition in response to exposure to body temperature and subsequently expanded to the expanded position by inflation of the balloon. In another embodiment, the vascular device is expandable to the expanded position as the device is substantially simultaneously exposed to body temperature and the balloon is inflated. The vascular device can be connected to the balloon. A pair of looped sutures can be provided to connect the vascular device to the balloon, the sutures separable from the vascular device upon expansion of the balloon to a predetermined size.

The present invention also provides a method for treating venous valve insufficiency comprising:

inserting a delivery device and a vascular device into a target vessel adjacent valve leaflets of the vessel;

deploying the vascular device to an enlarged diameter to securely engage an internal wall of the vessel; and

reducing the diameter of the vascular device to move the vessel wall radially inwardly and bring the valve leaflets closer together.

In one embodiment, the method further includes the step of deploying the vascular device to a first expanded diameter prior to deploying the vascular device to the enlarged diameter, wherein the first expanded diameter is less than the enlarged diameter. The step of deploying the vascular device to the enlarged diameter can include the step of inflating a balloon positioned within the device. The step of deploying the vascular device to the first expanded diameter preferably comprises the step of exposing the vascular device from a delivery sheath to enable the vascular device to return to a shape memorized configuration in response to being warmed by body temperature. In another embodiment, the step of deploying the vascular device to an enlarged diameter comprises

releasing the vascular device from the delivery device to enable it to return to a shape memorized condition and substantially simultaneously inflating a balloon.

The step of deploying the vascular device to an enlarged diameter can move a plurality of penetrating tips of vessel engaging members of the vascular device to a position substantially perpendicular at another angle to a longitudinal axis of the vascular device to engage the internal wall of the vessel.

The present invention also provides a method of approximating vein valve leaflets comprising:

inserting a vascular device of shape memory material in a collapsed configuration intravascularly to a target vessel;

actuating an expandable member to expand the vascular device to a further expanded configuration to enable wall engaging members of the device to retain the internal vessel wall; and

contracting the expandable member to allow the vascular device to contract towards it memorized expanded configuration to bring the valve leaflets closer together.

In one embodiment, the method further comprises the step of releasing the vascular device from a delivery sheath to enable it to return to its memorized expanded configuration prior to the step of actuating the expandable member. In another embodiment, the device returns to the memorized expanded configuration in response to exposure to body temperature and the step of actuating the expandable member to expand the vascular device occurs substantially simultaneously with exposure of the device to body temperature.

The wall engaging members preferably each have penetrating tips and the step of actuating the expandable member causes the penetrating tips disposed on a proximal portion and a distal portion of the vascular device to secure the internal vessel wall.

In the foregoing methods the delivery device can be inserted to a position upstream (with respect to blood flow) of the valve leaflets to deliver the vascular device upstream of the valve leaflets. Alternatively it can be inserted to a position downstream of the valve leaflets to deliver the vascular device downstream of the valve leaflets. The

delivery device can be inserted through the jugular vein or femoral vein into the popliteal vein or the saphenous vein, or directly into these veins.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

Figure 1 is a perspective view of a first embodiment of the vascular device of the present invention shown in the expanded configuration;

Figure 2 is a side view of the vascular device of Figure 1 in the expanded configuration;

Figure 3 is another side view of the vascular device in the expanded configuration, rotated 45 degrees with respect to Figure 2;

Figure 4 is a front view of the vascular device of Figure 1 in the expanded configuration;

Figure 5 is a perspective view of the vascular device of Figure 1 shown in the collapsed configuration for delivery within the vessel;

Figure 6 is a side view of the vascular device of Figure 1 in the collapsed configuration;

Figure 7 is another side view of the vascular device in the collapsed configuration, rotated 45 degrees with respect to Figure 6;

Figure 8 is a perspective view of an alternate embodiment of the vascular device of the present invention shown in the expanded configuration;

Figure 9A is a side view of the vascular device of Figure 8 shown in the expanded configuration;

Figure 9B is a side view similar to Figure 9A except showing an alternate embodiment where the vessel engaging members extend at an angle into the vessel wall;

Figure 10 is a perspective view of the vascular device of Figure 8 in the collapsed configuration for delivery within the vessel;

Figure 11 is a side view of the vascular device of Figure 8 in the collapsed configuration;

Figure 12 illustrates one method of insertion of the vascular device of Figure 1 showing the delivery catheter inserted directly into the popliteal vein in an antegrade direction;

Figure 13 illustrates an alternate method of insertion of the vascular device of Figure 1 through the jugular vein for retrograde insertion into the popliteal vein;

Figure 14 illustrates another method of insertion of the vascular device of Figure 1 showing the delivery catheter inserted through the right femoral vein for retrograde access to the popliteal vein;

Figure 15 illustrates yet another method of insertion of the vascular device of Figure 1 showing a contralateral approach wherein the delivery catheter is inserted through the left femoral vein for advancement around the iliac vein for retrograde insertion into the right popliteal vein;

Figure 16 shows a side view of the delivery catheter for the vascular device of Figure 1, with the vessel wall shown in section, illustrating antegrade insertion of the delivery catheter in the popliteal vein;

Figure 17 is a view similar to Figure 16 showing initial withdrawal of the sheath in the direction of the arrow to partially expose the vascular device of Figure 1;

Figure 18 is a view similar to Figure 16 showing the vascular device of Figure 1 expanded within the vessel, upstream (with respect to blood flow) of the valve leaflets, after the sheath has been fully withdrawn;

Figure 19 is a view similar to Figure 16, showing the vascular device of Figure 1 expanded by a balloon so the vessel engaging members penetrate and retain the vessel wall;

Figure 20 is a view similar to Figure 16, after the balloon is deflated and the catheter withdrawn from the vessel, showing the vascular device returned to its original position pulling the vessel wall together and bringing the valve leaflets into apposition;

Figures 21A-21C are transverse cross-sectional views of the vascular device of Figure 1 showing its interaction with the vessel wall during delivery and placement, wherein

Figure 21A corresponds to the initial position of the vascular device in Figure 18 wherein the vessel engaging members have not penetrated the vessel wall (the balloon has been omitted for clarity);

Figure 21B corresponds to the position of the vascular device in Figure 19 wherein the balloon has been inflated to radially expand the device to a second expanded position to enable the vessel engaging members to penetrate the vessel wall; and

Figure 21C corresponds to the position of the vascular device in Figure 20 wherein the balloon has been deflated and the device returns to the first expanded position bringing the vessel wall radially inwardly;

Figure 22 shows a side view of the delivery device for the vascular device of Figure 1, with the vessel wall shown in section, illustrating as an alternative, retrograde insertion of the delivery device in the popliteal vein;

Figure 23 is a view similar to Figure 22 showing initial withdrawal of the sheath in the direction of the arrow to partially expose the vascular device of Figure 1;

Figure 24 is a view similar to Figure 22 showing the vascular device of Figure 1 expanded within the vessel, upstream of the valve leaflets, after the sheath has been fully withdrawn;

Figure 25 is a view similar to Figure 22, showing the vascular device of Figure 1 expanded by a balloon so the vessel engaging members penetrate and retain the vessel wall;

Figure 26 is a view similar to Figure 22, after the balloon is deflated and the catheter withdrawn from the vessel, showing the vascular device returned to its original position pulling the vessel wall together and bringing the valve leaflets into apposition;

Figure 27 is a side view of an alternative embodiment of the vascular device in the expanded position shown within a vessel (the vessel wall is shown in section);

Figure 28 is a view similar to Figure 27 showing a balloon expanding the vascular device so the hooks penetrate the vessel wall;

Figure 29 is an enlarged view of the hook of the device of Figure 27 embedded in the vessel wall;

Figure 30 shows a side view of the delivery catheter for the vascular device of Figure 1, with the vessel wall shown in section, illustrating as another alternative, antegrade insertion of the delivery catheter in the popliteal vein for positioning of the vascular device downstream of the valve leaflets;

Figure 31 is a view similar to Figure 30 showing initial withdrawal of the sheath in the direction of the arrow to partially expose the vascular device of Figure 1;

Figure 32 is a side view of an alternate embodiment of the delivery system of the present invention having a restraint, the view being similar to Figure 23 in showing the vascular device expanded within the vessel, upstream of the valve leaflets, after the sheath has been withdrawn;

Figure 33 is a view similar to Figure 32, showing the vascular device of Figure 1 expanded by a balloon so the vessel engaging members penetrate and retain the vessel wall, and the restraint being severed by expansion of the balloon; and

Figure 34 is a transverse cross-sectional view of the vascular device of Figure 1 with the restraint of Figure 32 shown expanded to the memorized position substantially simultaneously with expansion of the balloon.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now in detail to the drawings where like reference numerals identify similar or like components throughout the several views, Figures 1-7 illustrate a first embodiment of the vascular device of the present invention and Figures 8-11 illustrate a second embodiment of the vascular device of the present invention. The devices, designated generally by reference numerals 10 and 100, are expanded to engage the internal wall of the vessel and contracted to pull the vessel walls radially inwardly. By pulling the vessel wall radially inwardly, the valve leaflets within the vessel are pulled closer together to a functional condition.

Figures 1-4 illustrate vascular device 10 of the first embodiment in the expanded configuration and Figures 5-7 illustrate vascular device 10 in the collapsed configuration. Vascular device 10 is preferably composed of a shape memory material, such as a nickel-titanium alloy commonly known as Nitinol, so that in its memorized configuration it assumes the shape shown in Figure 1. This shape memory material characteristically

exhibits rigidity in the austenitic state and more flexibility in the martensitic state. To facilitate passage from the delivery catheter, the shape memory device is maintained in a collapsed configuration inside a delivery sheath as described in more detail below, where it is cooled by a saline solution to maintain the device below its transition temperature. The cold saline maintains the temperature dependent device in a relatively softer condition as it is in the martensitic state within the sheath. This facilitates the exit of device 10 from the sheath as frictional contact between the device and the inner wall of the sheath would otherwise occur if the device was maintained in a rigid, i.e. austenitic, condition. When the device 10 is released from the sheath to the target site, it is warmed by body temperature, thereby transitioning in response to this change in temperature to an austenitic expanded condition.

Device 10 is preferably formed from a tubular member, preferably by laser cutting. Device 10 includes a proximal portion 12, and intermediate portion 14 and a distal portion 16. In the expanded condition, the device 10 has four substantially diamond shaped cells 17 forming substantially diamond shaped openings 18 at the proximal portion 12 and four substantially diamond shaped cells 15 forming substantially diamond shaped openings 20 at the distal portion 16. The end regions 19 of the cells 18, and the end regions 21 of the cells 20 are bent outwardly from the plane of the remainder of the cell, in a direction away from the longitudinal axis of the vascular device 10. This better enables the vessel engaging members, described below, to engage the vessel walls.

The intermediate portion 14 is formed of four substantially diamond shaped cells forming substantially diamond shaped openings 22 arranged around a 360 degree arc of the cylindrical tubular member 10, with a longitudinal strip 24 extending through to bisect each cell. Thus, four symmetric bisected cells 23 are formed. Each longitudinal strip 24 has a vessel engaging member 28 extending therefrom to engage the vessel wall as will be described below. In the expanded condition, the longitudinal strip 24 buckles radially outwardly, away from the longitudinal axis of the vascular device 10, to enable the center vessel engaging members 28 (described below) to engage and secure the internal vessel wall.

The geometry of the vascular device 10 can also be appreciated with reference to the collapsed configuration of the vascular device 10 shown in Figure 5-7. As shown, the

device 10 is in the form of a cylinder with a reduced diameter. Each longitudinal strip 24 has a cutout 27 to form vessel engaging member 28. The longitudinal strip 24 is tapered in width "w" at its opposing ends 29 which connect to the framework. The longitudinal slot 30 on each side of the strip 24 is substantially straight and has enlarged oval-like regions 32 at opposing ends. The outer wall 34 of each longitudinal slot 30, i.e. the wall of slot 34 spaced further from the longitudinal strip 24, is joined to the outer wall 34 of an adjacent longitudinal slot 30 by transverse rib 36. Each rib 36 forms one vertex of a cell 15 and one vertex of a cell 17 when expanded. The cell openings 18 and 20 in the collapsed configuration as shown in Figure 6, have, respectively, a narrowed elongated portion 20a, 18a, and a widened portion 20b, 18b with flared out regions 20c, 18c, to form the diamond shaped openings having bent end regions 21, 19 when device 10 is expanded. The flared out regions 20c, 18c enable the formation of such bent regions 21, 19.

A vessel engaging member extends from the framework of each of the cells 15 and 17. The vessel engaging member is preferably in the form of a hook with a penetrating tip and a barb.

More specifically, a vessel engaging member 40 extends outwardly and distally from the frame of each of the four cells 15 at the distal portion 16 of the device 10. In the collapsed configuration of device 10, each member 40 preferably extends generally parallel to the longitudinal axis of vascular device 10 and in substantially the same plane as the corresponding rib 36 at the opposing end.

Similarly, vessel engaging members 42 extend outwardly and proximally from the framework of each of the four cells 17 at the proximal portion 12 of the device 10. In the collapsed configuration of device 10, each member 42 preferably extends generally parallel to the longitudinal axis of vascular device 10 and in the same plane as the corresponding rib 36 at the opposing end

The four vessel engaging members 28 formed in the middle (intermediate) portion 14 in the collapsed configuration lie substantially parallel the longitudinal axis of the device 10 and in the same plane as the longitudinal strip 24 from which it is formed.

Each of the vessel engaging members 28, 40 and 42, are preferably in the form of a hook having a penetrating tip 29, 41 and 43 to pierce the vessel wall and a barb 31, 45

and 47, respectively, to help retain the vessel wall. The sharp penetrating tips 29, 41, 43 penetrate the vessel wall in a radial direction and hold the vessel against axial movement with respect to the device 10; barbs 31, 45, 47, restrict radial movement of the vessel with respect to the device 10, thereby together securely retaining (grasping) the vessel wall for radial inward movement described below.

It should be understood that although four vessel engaging members 42, 40, 28 are described extending from the proximal and distal cells 17, 15 and from the center longitudinal strips 24, respectively, a fewer or greater number of vessel engaging members can be provided as long as they achieve the vessel retaining function as described in more detail below.

When the vascular device 10 expands, members 28, 40 and 42 are moved to a shape memorized orientation bent outwardly at an angle, preferably about 90 degrees, with respect to the longitudinal axis "A" of the device 10 with regions 19 and 21 bending out of the plane to increase the distance the members can extend from the center to the vessel wall. Longitudinal strips 24 buckle radially outwardly, and members 28 bend outwardly at an angle, preferably about 90 degrees, with respect to the longitudinal axis, to engage the vessel wall. Although 90 degree angles are shown, clearly other angles are contemplated. Note that due to the geometry of the device 10, the points at the outer edge come inwardly axially, shortening the length of the device, and the center strut (strip) 24 buckles radially outwardly. The buckling extends the radial reach of the device 10. Note also that in the expanded configuration, the tips of the vessel engaging members terminate at substantially the same distance from the longitudinal axis of the device 10. The length of the end hooks is preferably the same as the length of the middle hooks; the bent regions 19, 21 accommodate for the buckling of strut 24. Due to the laser cut configuration, foreshortening, i.e. the reduction in length of the device in response to expansion, is reduced.

By way of example, for use for instance in an unhealthy dilated vessel of 14 mm. the length of the vascular device 10 in the collapsed configuration could be about 3cm and the outer diameter about 3.5mm. In the memorized expanded configuration, the length decreases to about 2.8cm and the transverse cross-sectional dimension increases to about 12mm, 15.5 mm if the 1.7mm hooks are included. Note that the length change is

due mostly to the buckling strip and the bent regions since the amount of foreshortening is minimized. These dimensions are provided by way of example as other dimensions are clearly contemplated by the present invention and use in different size vessels is also contemplated.

An alternate preferred embodiment of the vascular device of the present invention is shown in Figures 8-11, with Figures 8 and 9 showing the device in the expanded configuration and Figures 10-11 showing the collapsed configuration for delivery to the vessel.

Turning first to Figures 10 and 11, the device 100 is preferably laser cut from a cylindrical tube, forming a series, e.g. ten, of symmetrical longitudinal strips 102 terminating at opposite ends with vessel engaging members 110, 112. Each strip 102 has a longitudinal slot 104 formed therein having a uniform width throughout its length. Adjacent strips 102 are joined by transverse ribs or struts 106, creating a gap 108, 109 on either side of the ribs 106 between strips 102. Consequently, the device can be considered as forming one centrally located column of slots 104 with ribs 106 in axial alignment and slots 104 in axial alignment.

The vessel engaging members 110 and 112 are preferably in the form of hooks as described above in the first embodiment with each vessel engaging member 110 having a penetrating tip 114 and barb 116 and each member 112 having a penetrating tip 118 and barb 119. The penetrating tips 114 and 118 penetrate the vessel wall and prevent axial movement while the barbs 116, 119 restrict radial movement. In the collapsed configuration, as shown, the vessel engaging members 110, 112 are substantially parallel to the longitudinal axis of device 100, lying in the same plane as the respective longitudinal strip 102.

As shown, the cylindrical tubular member is formed into ten longitudinal strips 102 with ten hooks 110 at the proximal end 105 and ten hooks 112 at the distal end 107. Although ten longitudinal strips and ten vessel engaging members are shown on each end, it should be appreciated that fewer or greater number of longitudinal strips and vessel engaging members can be utilized. Moreover, not all of the longitudinal strips need to terminate in vessel engaging members, provided a sufficient number of strips have vessel engaging members to adequately secure the vessel.

The structure of the vascular device 100 is shown in its first expanded configuration in Figures 8 and 9. Vascular device 100, like device 10, is composed of a shape memory material, such as Nitinol, so that in its memorized configuration it assumes the shape shown in Figure 8. The shape memory device is maintained in a collapsed configuration inside a sheath as described in more detail below, where it is cooled by a saline solution to maintain the device below its transition temperature. When the device 100 is delivered to the target site and released from the sheath, it is warmed by body temperature, thereby transitioning in response to this change in temperature to an austenitic expanded condition. Maintenance of the device in its softened martensitic state within the sheath facilitates delivery to the vessel as frictional contact between the device 100 and the internal walls of the delivery sheath would otherwise occur if the device was retained within the sheath in its austenitic condition.

When expanded, longitudinal slots 104 form substantially diamond shaped cells 120 with substantially diamond shaped openings 122. Upon expansion, the vessel engaging members 110 and 112 extend at an angle, preferably about 90 degrees, to the longitudinal axis of the vascular device 10 to enable the vessel engaging members 110 and 112 to engage and secure the vessel wall (see e.g. Figure 9A). However, it is also contemplated that the vessel engaging members 110',112' could extend at a different angle, for example about 60 degrees, as shown in the alternative embodiment of Figure 9B.

As the device moves from the collapsed configuration to the expanded configuration, it shortens in axial length as the diameter increases. For example, in one embodiment the length of the vascular device 100 in the collapsed configuration is about 1.8cm and the diameter is about 3.5 mm. In the expanded configuration, the length decreases to about 1cm, mainly due to the hooks bending up as foreshortening is minimized, and the diameter in the memorized expanded configuration increases to about 12 mm. (15.5.if the 1.75 mm hook length is included). These dimensions are provided by way of example as other dimensions are clearly contemplated.

Turning to the method of use of the vascular devices of the present invention, the insertion of vascular device 10 will be described, it being understood that vascular device

100 would be inserted in the same manner and expanded and retracted in the same manner as device 10.

There are several different methods of insertion of the vascular device of the present invention for treating venous valve insufficiency of the popliteal or saphenous vein. Figures 12-15 illustrate examples of some of these approaches by illustrating various access vessels for the delivery devices to reach these veins. In Figure 12, the catheter 200 is placed into the popliteal vein "P" in the patient's leg "G" and advanced to a region adjacent the leaflets "T" to deploy the vascular device upstream of the leaflets. The delivery catheter is thus delivered in an antegrade fashion, with the tip extending downstream of leaflets "T" to deploy the device just upstream (defined in reference to the direction of blood flow) of the leaflets.

In the approach of Figure 13, the catheter 210 is inserted through the right jugular vein "J", where it will be advanced through the superior and inferior vena cava, past the iliac vein "I", through the femoral vein "F" and into the popliteal vein "P" through leaflets "L" in a retrograde fashion, i.e. opposite the direction of blood flow. The delivery catheter 210 would thus extend through the leaflet region just upstream of the leaflets. In Figure 14, the catheter 220 is placed in the right femoral vein "F", where it will be advanced in a retrograde manner to the popliteal vein "P" in the manner described above with respect to Figure 13.

In the contralateral approach of Figure 15, the catheter 230 is inserted through the left femoral vein "H" where it will be advanced around the iliac vein "I" and through the left femoral vein "F" into the popliteal vein "P."

Each of the delivery catheters 200, 210, 220 and 230 has respective tubing 202, 212, 222 and 232, with a stopcock 204, 214, 224 and 234 to control saline infusion through the catheter to maintain the vascular device 10 (or device 100) in the cooled martensitic collapsed configuration for delivery. Inflation port 206, 216, 226 and 236 provides for fluid infusion to inflate the balloon which is mounted on the catheter shaft and positioned within the device 10. The outer sheath of the delivery catheter slides with respect to the catheter shaft to expose the vascular device. Guidewire port 208, 218, 228 and 238 enables insertion of a conventional guidewire (not shown) to guide the delivery catheter intravascularly to the target site. A conventional access or introducer sheath (not

shown) would be inserted through the skin and into the access vessel, and the respective delivery catheter would be inserted into the access vessel through the introducer sheath.

Figures 16-20 illustrate the method steps of insertion of the vascular device 10 in an antegrade fashion intravascularly in the popliteal vein "P". Catheter or delivery sheath 200 is inserted over a conventional guidewire (not shown) so the distal tip 201 of the catheter shaft extends past, i.e. downstream of the valve leaflets L extending annularly from vessel wall "V" as shown in Figure 16. As can be appreciated, since there is a gap "a" between the valve leaflets "L", the valve cannot function properly because the leaflets cannot properly close to prevent backflow. Also, due to the malfunctioning of the valve, the vessel wall becomes dilated as shown as the weight and pressure of the backflow blood pushes out the vessel wall.

Once the position of the sheath 200 is confirmed by venography, intravascular ultrasound, or other means, the sheath 205 is withdrawn with respect to catheter tip 201 in the direction of the arrow of Figure 17, exposing the vascular device 10. When the sheath 205 has been fully withdrawn to expose the device 10, the device is warmed by the body temperature and transitions to its austenitic phase and the first memorized expanded configuration of Figure 18.

Next, a balloon member 240 on catheter shaft 209 which is positioned within device 10 is inflated via introduction of fluid through inflation lumen 206 (Figure 12) to further expand the device 10 to a second expanded configuration shown in Figure 19. That is, the device is expanded to a larger diameter than the diameter in its memorized configuration of Figure 18 so that vessel engaging members 28, 40 and 42 will engage the vessel wall "V" with the sharp tips and barbs penetrating the vessel wall to firmly grasp and secure it. This securement restricts both radial and axial movement of the vessel to enhance retention by the device 10.

After retention of the vessel wall as in Figure 19, the balloon is deflated (and the catheter 200 removed), resulting in the device 10 contracting from the second expanded configuration towards its memorized configuration. Preferably, the device 10 will return to substantially the same diameter as the first (memorized) expanded configuration. As contracted, the device 10, due to the engagement of the vessel engaging members with the internal wall of the vessel, pulls the vessel wall radially inwardly, thereby pulling the

leaflets radially inwardly to the position of Figure 20 to close gap "a". As can be appreciated, the vessel wall is no longer dilated and the valve leaflets are sufficiently approximated such that their tips contact to block backflow and their function is therefore restored. The device 10 remains inside the vessel, maintaining the approximation of the vessel wall to maintain the proper functioning of the leaflets.

The changing diameters of the vascular device 10 can also be appreciated by reference to the transverse cross-sectional views of Figure 21A-21C. The delivery device has been removed for clarity. More specifically, Figure 21A corresponds to the initial position of the vascular device 10 in Figure 18 wherein the device 10 has been delivered to the target vessel, and has expanded to the first expanded (memorized) configuration but the vessel engaging members have not penetrated the vessel wall. It should be appreciated that in this configuration the vessel engaging members may or may not be in contact with the vessel wall, but in either case, do not fully penetrate and secure the vessel to the same extent as in the second position. As shown, by way of example, the unhealthy dilated vessel can have an internal diameter D1 of approximately 14mm. The balloon is not shown in Figure 21A for clarity.

Figure 21B corresponds to the position of the vascular device in Figure 19 wherein the balloon has been inflated to radially expand the device 10 to a second expanded position to enable the vessel engaging members to penetrate and retain (secure) the vessel wall. In this configuration, the vessel wall is further expanded to a diameter D2 of about 16mm, as the device is expanded to a diameter of about 16mm, with the hooks extending an additional 2mm so the device is expanded to 20mm.

Figure 21C corresponds to the position of the vascular device 10 in Figure 20 wherein the balloon has been deflated and the device contracted to bring the vessel wall radially inwardly. The internal vessel wall diameter will preferably be about 12mm to close the gap between the leaflets. The diameter of the vascular device 10 preferably returns to the same diameter as in Figure 21A, e.g. about 12mm. As can be seen the device 10 abuts the vessel wall V.

Figures 22-26 illustrate retrograde insertion of the vascular device 10. In this approach the delivery catheter, e.g. catheter 210, is inserted in a direction against the blood flow so tip 211 extends past the valve leaflets "L" in the popliteal vein "P" and the

catheter 210 is positioned so the device 10 will be deployed upstream of the leaflets. The deployment of the device 10 is otherwise the same as in Figures 16-20. That is, sheath 215 of the delivery device 210 is retracted in the direction of the arrow of Figure 23, to expose the device 10. Full retraction and removal of the sheath 215 to expose the device to the warmer body temperature enables it to expand to its memorized (first expanded) configuration of Figure 24. Subsequent expansion of balloon 250 (Figure 25) causes the vessel engaging members 42, 28, 40 to penetrate and retain the vessel wall so that upon deflation of the balloon, the device 10 returns to the memorized configuration of Figure 26 pulling the vessel wall inwardly and bringing the valve leaflets "L" closer together into apposition so the tips can contact. The changing diameters would also correspond to the aforedescribed transverse cross-sections of Figure 21A-21C.

As can be appreciated, device 10 and device 100 are each symmetrical so that the "proximal" and "distal" portions are identified herein for convenience.

Figures 27-29 illustrate an alternate embodiment of the vascular device designated generally by reference numeral 300. This shape memory device 300 is illustrated and described in Provisional patent application No. 60/214,120, filed June 6, 2000, the entire contents of which are incorporated herein by reference. Device 300 is placed within vessel V, e.g. the popliteal vein, to approximate leaflets "L" which as shown in Figure 27 are not functioning properly because the tips L1 are spaced apart. In its first expanded configuration corresponding to its memorized shape of Figure 27, hooks 314 have not penetrated the vessel wall. The device 300 is formed by struts 302 as described in detail in the '120 application. Hooks 314, affixed to struts 302 at region 304 are crescent shaped and have pointed ends 306 with barbed portions 308.

In the expanded configuration of Figure 28, balloon 322 on shaft 324 of the delivery device has expanded the device 300 so that hooks 314 penetrate and securely engage the vessel wall "V". The balloon would then be deflated and the device 300 would return to its first expanded configuration bringing the vessel walls radially inwardly and bringing the valve leaflets into apposition in the same manner as described above with respect to vascular device 10.

Figures 30 and 31 illustrate an alternate method of placement of the vascular device. In this method, the vascular device 10 (or vascular device 100) is placed

downstream (with respect to the direction of blood flow) of the valve leaflets. The delivery catheter 210' is inserted in the same antegrade manner as described above with respect to Figure 16, except it is advanced sufficiently past the valve leaflets L to enable downstream delivery of the device 10. Once positioned as shown in Figure 31, the sheath 215' is withdrawn in the direction of the arrow, enabling the device 10 to expand to its memorized configuration. Vascular device 10 would then be further expanded by a balloon and then enabled to contract to its memorized configuration in the same manner as in Figures 18-20, the only difference being that the device10 would grasp the vessel wall downstream of the valve leaflets to pull the vessel wall radially inwardly to bring the leaflets into apposition.

It should be appreciated that the device 10 or device 100 could also be delivered in a retrograde fashion such as shown in Figures 13-15 for positioning of the device downstream of the leaflets L.

Figures 32-34 illustrate an alternative delivery system and method for vascular device 10 (or device 100 which can be delivered in the same manner). In this method, exposure of the vascular device to body temperature and expansion of the balloon occur substantially simultaneously. To facilitate placement, a restraint system for connecting the vascular device to the balloon is provided.

More specifically, balloon 250' has a pair of sutures 252 attached thereto at a proximal and distal portion which wrap around the vascular device 10 forming a loop of suture to connect the balloon and the device. Although two sutures, are shown, it is contemplated that one suture or more than two sutures can be utilized to connect the balloon 250' to the vascular device 10. Additionally, other restraint systems such as perforated strips can be utilized.

In the position of Figure 32, the sutures (only one of which is shown, the other suture still within the sheath 215') are loosely wrapped around the device. As the sheath 215' is retracted in the direction of the arrow, the balloon is inflated. Thus, as the sheath 215' is fully withdrawn, the device expands to the position of Figure 33, without the intermediate step required in the methods described above, i.e. without the step of Figure 24 which first allows the device to expand to the memorized configuration. As the balloon expands, the pressure against the sutures 252 breaks the suture loops, thereby

releasing them from the vascular device 10. This way, when the balloon 250' is deflated and withdrawn with the delivery catheter 210' from the body, the sutures 252 are removed as well. Upon deflation, the vascular device 10 returns to its memorized configuration to pull the vessel wall radially inwardly in the manner described above to assume a position like that of Figure 26.

Note that it is also contemplated that the balloon 250' can be inflated first within the sheath, followed by withdrawal of the sheath to expose the vascular device 10 to body temperature.

Additionally, the restraint system can also be utilized with the sequential method of deployment of Figures 16-20 and Figures 22-26. The restraint system, e.g. the sutures, would help prevent axial movement and help center the balloon with respect to the vascular device 10.

While the above description contains many specifics, those specifics should not be construed as limitations on the scope of the disclosure, but merely as exemplifications of preferred embodiments thereof. For example, instead of a balloon to expand the device to its second expanded diameter/condition, a mechanical means such as an expandable wire frame can be utilized. Also, instead of moving the sheath to expose the vascular device, the catheter can be advanced with respect to the sheath or both the catheter and sheath can move relative to each other in opposite directions. Those skilled in the art will envision many other possible variations that are within the scope and spirit of the disclosure as defined by the claims appended hereto.